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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,935	BATHE ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5,9 and 12-44 is/are pending in the application.
- 4a) Of the above claim(s) 13-30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5,9,12 and 31-34 is/are allowed.
- 6) ☒ Claim(s) 35-44 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. <u>8/2/04</u> <u>3/3/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on November 3, 2003), Applicant filed a response and amendment received on March 3, 2004. Said amendment amended Claims 4, 5, and 9, cancelled Claims 1-3, 6-8, 10, 11, and 28, and added new Claims 31-44. Applicant also filed a supplemental response on March 11, 2004 that amended the Abstract. Thus, Claims 4, 5, 9, and 12-44 are pending in the instant Office action. Claims 13-30 remain withdrawn from consideration as non-elected inventions. Claims 4, 5, 9, 12, and 31-44 will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the foreign applications 100 43 337.5 and 101 36 984.0 filed in Germany on September 2, 2000 and July 28, 2001, respectively as requested in the declaration. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. Translations of said priority documents have been received.

Information Disclosure Statement

3. The information disclosure statement filed on March 3, 2004 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Withdrawn- Objections to the Specification

4. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicant's amendment to the Abstract.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

5. Previous rejection of Claims 1-4, 6-8, and 28 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "from coryneform bacteria" is withdrawn by virtue of Applicant's amendment and/or cancellation of said claims. Moreover, this phrase is not in the newly pending claims.

6. Previous rejection of Claims 1-4, 6-8, and 28 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "coding for the sigM gene" is withdrawn by virtue of Applicant's amendment and/or cancellation of said claims. Moreover, this phrase is not in the newly pending claims.

7. Previous rejection of Claim 2 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "sigma factor M activity" is withdrawn by virtue of Applicant's cancellation of said claim. Moreover, this phrase is not in the newly pending claims.

8. Previous rejection of Claim 7 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "further comprising ... sense mutations that are neutral in terms of function" is withdrawn by virtue of Applicant's cancellation of said claim. Moreover, this phrase is not in the newly pending claims.

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9. Previous rejection of Claims 10-11 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “**the sigM gene**” (emphasis added) that indicates a particular *sigM* gene is withdrawn by virtue of Applicant’s cancellation of said claims. Moreover, this phrase is not in the newly pending claims.

10. Previous rejection of Claims 1-4, 6-8, and 28 under 35 U.S.C. 112, first paragraph, written description (undefined structure, lacking specific function), is withdrawn by virtue of Applicant’s amendment and/or cancellation of said claims. Moreover, the amended claims are drawn to products having particular structure in which the function is inherent (SEQ ID NO:1 or polynucleotide encoding SEQ ID NO:2); this is not the case for some of the new claims (see new rejections below).

11. Previous rejection of Claims 10-11 under 35 U.S.C. § 112, first paragraph, written description (undefined structure, lacking specific function), is withdrawn by virtue of Applicant’s cancellation of said claims. Moreover, new Claim 44 is not rejected under written description due to the additional language describing a specific sigM gene in the claim.

12. Previous rejection of Claims 1-4, 6-8, 10-11, and 28 under 35 U.S.C. § 112, first paragraph, scope of enablement (breadth of structure with function), is withdrawn by virtue of Applicant’s amendment and/or cancellation of said claims. While the amended claims no longer have enablement issues in view of the particular structural limitation in said claims, new claims requiring only fragments do have enablement issues (see new rejections below). Applicant

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presented no arguments except that the claims have been cancelled; related subject matter in a new claim was not addressed.

13. Previous rejection of Claims 10-11 under 35 U.S.C. § 112, first paragraph, scope of enablement (enhancement/overexpression breadth), is withdrawn by virtue of Applicant's cancellation of said claims. However, new Claim 44 has the same issue (see new rejection below). Applicant presented no arguments except that the claims have been cancelled; related subject matter in a new claim was not addressed.

14. Previous rejection of Claim 12 under 35 U.S.C. § 112, first paragraph, enabling deposit, is withdrawn by virtue of Applicant's amendment to the specification as well as Applicant's statement of irrevocability upon granting of a patent (see Remarks filed March 3, 2004).

Withdrawn - Claim Rejections - 35 U.S.C. § 102

15. Previous rejection of Claims 1-3, 6-8, and 28 under 35 U.S.C. § 102(a) as being anticipated by Pompejus *et al.* is withdrawn by virtue of Applicant's cancellation of said claims. No other arguments have been presented.

16. Previous rejection of Claims 1-11 and 28 under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.* is withdrawn by virtue of Applicant's filing of a certified translation of DE 100 43 337.5 (filed on September 2, 2000), which priority document discloses the claims subject matter. Thus, Nakagawa *et al.* (EP 1108790, published on June 20, 2001) is not considered prior art against the instant claims.

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17. Previous rejection of Claims 1-3 and 6-8 under 35 U.S.C. § 102(b) as being anticipated by Zhao *et al.* is withdrawn by virtue of Applicant's cancellation of said claims.

NEW ISSUES

Claim Objections

18. Claim 4 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 depends from Claim 9, which is drawn to a polynucleotide encoding a particular polypeptide. Since only DNA and RNA polynucleotides encode polypeptides, this further limitation of Claim 4 cannot further limit the subject matter of Claim 9.

19. Claim 36 is objected to for having a typographical error. Dependence on Claim 30 is inappropriate for Claim 36 since Claim 30 does not describe a vector. Claim 36 should depend from Claims 34 or 35 (only preceding vector claims). Since Claim 34 is the broadest, Claim 36 will be examined as if it depends from Claim 34. Correction is required. Claim 36 will be examined as if this correction has been made.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20. Claim 35 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if Claim 35 is claiming the vector or the vector only as it is found within the host cell (thus, claiming a host cell, not just the vector). The Examiner suggests --- wherein said vector is pEC-XK99sigMalex as deposited in DSM 14409--- for clarity.

Clarification is required.

21. Claims 38-43 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claims 38-39, it is unclear if the claimed polynucleotide comprises (a) at least 21[23] consecutive nucleotides of SEQ ID NO:1 or (b) the complete complement of SEQ ID NO:1 ... or if the claimed polynucleotide comprises (i) at least 21[23] consecutive nucleotides of SEQ ID NO:1 or (ii) *at least 21[23] consecutive nucleotides of the complete complement of SEQ ID NO:1*. If the latter is intended, the Examiner suggests using itemization for clarity. Clarification is required.

22. Claim 44 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “the sigma factor M gene consisting of a polynucleotide, which

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encodes ...SEQ ID NO:2" is unclear. Said polynucleotide cannot "consist" in the bacterium and be over-expressed since all expression requires some upstream sequence, a promoter, etc., and none of these can be adjacent to the sigM gene when it "consists" of a sequence encoding SEQ ID NO:2 (i.e., nothing attached to the polynucleotide encoding SEQ ID NO:2). Thus, the inclusion of the closed language renders the claim confusing. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

23. Claims 36-37 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims to generic host cells are not supported in the specification as originally filed. While the specification describes using coryneform host cells (see original claims) and, in the examples, using *E. coli* as a host cell, no generic host cell description is found. Applicant is required to delete the alleged new matter or to point out specific support (page and line number) for the alleged new matter in the specification as originally filed.

24. Claims 38-43 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 38 and 39 are drawn to polynucleotides comprising fragments of SEQ ID NO:1 in the absence of functional language.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification discloses a polynucleotide encoding sigM, a transcription factor, and particular fragments thereof. Applicants have fully described the genus relating to said SEQ ID NO with both sequence fragment limitations and functional limitations. However, the genus of the instant claims also contains polynucleotides within the sequence fragment limitations, but having different function. Moreover, a fragment of only 21 or 23 consecutive nucleotides cannot support the activity of the encoded full-length polypeptide as described in the instant specification and the art. Thus, the specification does not fully describe a genus that has

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sequence fragment limitations in the absence of functional limitations. Wherein probes are intended (see Claims 42-43), the Examiner suggests closed (consisting of) claim language. However, such claim language would be "opened" by the language of dependent Claims 40-41. Careful consideration of amended claim language is suggested.

25. Claims 38-43 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for fragments of SEQ ID NO:1, does not reasonably provide enablement for all polynucleotides comprising fragments of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant claims are drawn to polynucleotides and related products that comprise as little as 21 consecutive nucleotides of SEQ ID NO:1. To use all such polynucleotides would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of

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experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The instant specification teaches SEQ ID NO:2, a sigma factor protein from *C. glutamicum*, and SEQ ID NO:1, a *C. glutamicum* gene exactly encoding SEQ ID NO:2. The art includes few examples of sigM encoding genes, none of which are described in the instant specification. The art fully enables any DNA encoding SEQ ID NO:2 based on the degeneracy of the genetic code. However, the instant claims require only a small portion of SEQ ID NO:1, which portion is too small to maintain the sigma factor activity. Thus, the claims polynucleotides, when deviating significantly from SEQ ID NO:1 outside of the 21 consecutive nucleotides, can have any structure and any function. The specification indicates that such polynucleotides can be used as probes or primers; the Examiner agrees - up to a point. When a significant portion of the sequence outside of the consecutive sequence does not match a sigM gene, the ability of the claimed invention to hybridize to sigM genes (and act as a probe) is severely comprised and its use would be wholly unpredictable. Therefore, the instant claims are not enabled to the full extent of their scope. The Examiner suggests using closed and/or fragment claim language in Claims 38-41 to limit the claims to only pieces of SEQ ID NO:1 that can be used as hybridization probes.

26. Claim 44 is rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for coryneform transformed with an overexpression

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vector comprising a polynucleotide encoding SEQ ID NO:2, does not reasonably provide enablement for any coryneform overexpressing a polynucleotide encoding SEQ ID NO:2 (as per the definition of overexpression found in the specification). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The instant claims are drawn to coryneform overexpressing a polynucleotide encoding SEQ ID NO:2.

The factors to be considered in determining whether undue experimentation is required are summarized above.

The instant specification teaches a sigM gene from *C. glutamicum* and transformation techniques used for coryneform host cell. Thus, one of skill in the art could readily produce expression vectors of the disclosed gene for overexpression in recombinant coryneform. However, the claimed scope also includes using altered sigM genes such that the gene is overexpressed (i.e., changing RNA transcript stability, protein stability, etc., see paragraphs [0023] and [0039]). No examples, guidance, or direction is presented to enable one of skill in the art to produce such host cells. Moreover, it is wholly unpredictable how to produce such sigM genes for overexpression. Thus, the scope of the instant claims is not fully enabled.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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27. Claims 36-43 are rejected under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.* (EP 1108790). The instant claims are drawn to host cells comprising vectors that comprise SEQ ID NO:1 and to polynucleotides that are fragments of SEQ ID NO:1. Claims 36-37 are not supported by either the foreign priority document or the instant specification (see new matter rejection above) and, thus, cannot be granted priority prior to the instant filing date. Claims 38-43 do not have priority to the foreign filing date, which teaches probes of 15, 20, 30, 40, or 50 consecutive nucleotides only.

Nakagawa *et al.* teach SEQ ID NO:7069, a portion of which (299357-300567 bp) is equivalent to the full length of SEQ ID NO:1 (1-1211 bp) (see previously attached alignment). Nakagawa *et al.* also teach overexpression of the disclosed sequences in *C. glutamicum* host cells to produce the encoded polypeptides (see page 22).

28. Claims 38-43 are rejected under 35 U.S.C. § 102(a) as being anticipated by Pompejus *et al.* (WO 01/00843). The instant claims are drawn to polynucleotides that are fragments of SEQ ID NO:1 and related polynucleotide products. Claims 38-43 do not have priority to the foreign filing date as noted above.

Pompejus *et al.* teach SEQ ID NO:507 (3005-3075 bp) that matches SEQ ID NO:1 from 1-71 bp (see previously attached alignment). Pompejus *et al.* also teach overexpression of SEQ ID NO:507 in *C. glutamicum* to produce lysine using overexpression vectors (see page 8).

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Summary of Pending Issues

29. The following is a summary of the issues pending in the instant application:

- a) Claim 4 stands objected to under 37 C.F.R. § 1.75(c).
- b) Claim 36 stands objected to for having a typographical error.
- c) Claim 35 stands rejected under 35 U.S.C. § 112, second paragraph.
- d) Claims 38-43 stand rejected under 35 U.S.C. § 112, second paragraph.
- e) Claim 44 is rejected under 35 U.S.C. § 112, second paragraph.
- f) Claims 36-37 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.
- g) Claims 38-43 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
- h) Claims 38-43 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
- i) Claim 44 stands rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
- j) Claims 36-43 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.* (EP 1108790).
- k) Claims 38-43 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Pompejus *et al.* (WO 01/00843).

Other Cited Reference

30. The Examiner cites the following to complete the record:

- a) USPAP 2002/0197605 (Nakagawa *et al.*) is a U.S. filing related to EP 1108790 of record.

Conclusion

31. Claims 5, 9, 12, and 31-34 are allowed. Claims 4 are objected to. Claims 35-44 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Examiner
Art Unit 1652

June 21, 2004